DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

THROUGH: Vincent Tolino __/S/_____11/13/06
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Kathleen L. Walker __/S/_____11/3/06___
Chief, Integrity, Committee and Conference Management Branch
Division of Ethics and Management Operations, OMO
Center for Devices and Radiological Health

SUBJECT: Conflict of Interest Waiver for George W. Vetrovec, M.D.

I am writing to request a waiver for George W. Vetrovec, M.D., serving on the Circulatory System Devices Panel of FDA's Medical Devices Advisory Committee as a consultant, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under section 208(b)(3) may be granted by the appointing official where "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved" and where the individual has made a disclosure of the financial interests at issue. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Dr. Vetrovec a waiver under section 208(b)(3).

Section 208(a) prohibits Federal executive branch employees, including special Government employees, from participating personally and substantially in matters in which the employee or his employer has a financial interest. Since Dr. Vetrovec is a special Government employee, this individual is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to him or his employer.

Dr. Vetrovec has been asked to participate in the Panel's discussion of issues related to stent thrombosis in coronary drug-eluting stents (DES). These stents contain drugs that potentially reduce the chance the arteries will become blocked again. The discussion will also include issues regarding the association between DES thrombosis and the [----------]. These matters are coming before the Circulatory System Devices Panel for consideration and are particular matters of general applicability. Thirty-three firms are currently identified as manufacturers of the stent, drug or delivery components and 18 firms produce devices that are alternative technologies to drug-eluting stents.

Dr. Vetrovec has advised the FDA that he has financial interests which could potentially be affected by his participation in this matter. He reported that his [----]stock [---------] with [-------] includes:

[--] shares of [-------] stock, valued at approximately [----];
[--] shares of [----------]. stock, valued at approximately [----]; and
[--] shares of [----------] stock, valued at approximately [----].

Dr. Vetrovec's [-----] owns [--]shares of stock in [----------]; valued at approximately [-----]. Each of these holdings represents [----------]of his net worth.
Relevant to this meeting, [----------] [----------] include DES and alternative technologies to treat the same patient population. [----------] is the parent of [----------], manufacturer of [----------] for use on DES system.

Dr. Vetrovec also reported a consulting arrangement with [----------]. This arrangement has been [----------] and involves his review of [----------], which includes DES. Approximately [----]meetings are scheduled [----] and he receives [----] for each meeting he attends. Travel expenses are included in these fees.

The functions of the committee, as stated in its Charter, are to review and evaluate available data concerning the safety and effectiveness of marketed and investigational devices and advise the Commissioner of Food and Drugs regarding recommended classification of these devices into one of three regulatory categories; recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advise on any possible risks to health associated with the use of devices; advise on formulation of product development protocols and review premarket approval applications for those devices classified in the premarket approval category; review classification as appropriate; recommend exemption to certain devices from the application of portions of the Act; advise on the necessity to ban a device; and respond to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

As a consultant to the Circulatory System Devices Panel, Dr. Vetrovec potentially could become involved in matters that affect [----------], [----------],[----------], and [---------- -------]and their subsidiaries. Under section 208, Dr. Vetrovec is prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. §208(b)(3) to grant a waiver permitting this individual to participate in such matters, as you deem appropriate.

For the following reasons, I believe it would be appropriate for you to grant a waiver to Dr. Vetrovec allowing him to participate in matters identified below.

First, the issues to be addressed by the Panel are matters of general applicability, involving an entire class of products and granting no advantage to any individual manufacturer. Therefore, the Panel recommendations would not be expected to have a significant financial impact on any specific firm and the potential perception of bias on the part of the SGE should be mitigated.

Second, his stockholdings represent [----------] of his net worth. Also, given the fact that he has a [----------] in [----------] manufacturers and competitors, the likelihood that his judgment will be influenced by these interests should be minimized.

Third, [-------], [----------], [----------] and [----------] are very large, well-established firms with highly diversified product lines and global presence. Therefore, the SGE's recommendations should not be expected to affect the viability of these large firms or significantly alter their stock values.

Fourth, the Panel's role is advisory in nature and the Agency officials making the decisions are not bound by the recommendations of the Panel. Therefore, the Agency will take into consideration the SGE's reported interests when making a final decision.

Lastly, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee. Also, the committee's intended purpose would be significantly impaired if the Agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interest and affiliations they may have acquired as a result of their demonstrated abilities. In addition to administrative, research and teaching activities, Dr. Vetrovec is an active clinical cardiologist, including performing catheterization and interventional procedures. Dr. Vetrovec is Chairman of the Division of Cardiology, Director of the Adult Cardiac Catheterization Laboratory, and the Department of Internal Medicine's Associate Chairman of Medicine for Clinical Affairs at Virginia Commonwealth University. He is an experienced interventional and clinical cardiologist who is very interested in the patient perspective. His special expertise is in the area of pharmacokinetics studies, which are critical to understanding the drug component of drug-eluting stents and its metabolism once in the body. Questions have been raised about the relationship of the drug component to stent thrombosis. Dr. Vetrovec's experience in this area will be crucial to the discussion of thrombosis etiology.

Accordingly, I recommend that you grant Dr. Vetrovec a waiver allowing him to participate fully in all official matters before the Panel regarding issues related to stent thrombosis in coronary drug-eluting stents. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Vetrovec outweighs the potential for a conflict of interest created by the financial interest involved.

CONCURRENCE: __/S/_____ 11/13/06
Vincent Tolino Date
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

DECISION:

____X____ Waiver granted based on my determination made in accordance with section 208(b)(3), that the need for the individual's services outweighs the potential for conflict of interest created by the financial interest attributable to the individual.

_____ Waiver denied.

_/S/_____ 11/16/06
Randall Lutter, Ph.D. Date
Associate Commissioner for Policy
and Planning